2nd Gen Oxitec (OX5034) EUP Application and September 2019 Nature Research Paper

Issue: Evans *et al.*, 2019 paper in Nature Research[1] contradicts Oxitec's hypothesis that mosquito lab strain genes will disappear quickly from the environment. The data and methods appear to be scientifically sound and increases OPP concern regarding the introduction of mosquito lab strain genes into natural mosquito populations for the pending Oxitec EUP application.

Action in Review

- OCSPP is currently reviewing an application Oxitec submitted for an Experimental Use Permit to test the efficacy their 2nd Generation OX5034 mosquitoes on March 11, 2019. If approved by EPA, Oxitec would conduct experimental trials in Florida and Texas next year.
- Notice of Receipt published September 11, 2019 beginning a 30-day public comment period.
- EPA has received 41 public comments so far, many of which reference the recent Evans *et al.*, 2019 publication including two comments requesting an extension of the comment period to assess the results in the Evans *et al.*, 2019 publication in relation to the current application.

Background

- Oxitec withdrew their prior applications for an EUP and registration for OX513A, the 1st generation product. Their application for OX513A was approved in Brazil and mosquitoes were subsequently released.
- OCSPP has completed the initial screening level review of Oxitec's OX5034 and has moved the application into full review.
- 2nd Gen Oxitec mosquitoes (OX5034) allow for male survival and subsequent reproduction in the environment and thus the likely introduction of lab strain genes into the wild mosquito population (i.e., introgression).
- OCSPP identified the possible movement of genes from the released OX5034 mosquitoes into the wild mosquito populations as a potential issue in pre-submission meetings and again after submission of the application.
- Evans *et al.*, 2019 (published Sept 10) contradicts Oxitec's hypothesis that lab genes will disappear quickly from the environment. The article examines Oxitec's 1st generation GE mosquito where this is less of a risk. Yet, it demonstrates the movement of genes is occuring.
- This issue is credible and deserves scientific scrutiny since the current EUP application before OCSPP (2nd generation OX5034) is expected to have a greater risk of this happening.

Potential next steps

Ex. 5 Deliberative Process (DP)

[1] [HYPERLINK "https://www.nature.com/articles/s41598-019-49660-6"]